UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

08/03/07

DP BARCODE:	D340393	
MRID:	None	
SUBJECT:	Sterilex Ultra Disinfectant Cleaner Solution 1	
REG. NO. OR FILE SYMBOL:	63761-8	
DOCUMENT TYPE:	Product Chemistry Review	
Manufacturing-use [] OR	End-use Product [X]	
INGREDIENTS (PC Codes)	n-Alkyl (60% C14, 30% C16, 5% C18, 5% C12) dimethyl benzyl ammonium chloride (069104); n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride (069154); Hydrogen peroxide ( )	
CAS Number:	(53516-76-0); (85409-23-0)	
TEST LAB:	None.	
SUBMITTER:	Sterilex Corp	
GUIDELINE:	None	
COMMODITIES:	Formulation	
REVIEWER:	Juan F. Negrón	ORGANIZATION: AD
APPROVER:	Karen P. Hicks	APPROVED DATE: 8/7/07
COMMENT:		

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

08/02/07

TO:	Marshall Swindell / Karen Leavy PM Team 33
FROM:	Juan F. Negrón, Chemist Product Science Branch, CT Team Antimicrobial Division (7510P)
THRU:	Karen P. Hicks, CT Team Leader Product Science Branch Antimicrobial Division (7510C)
THRU:	Michele E. Wingfield, Chief Product Science Branch Antimicrobial Division (7510C)
APPLICANT:	Sterilex Corp
Action code:	345
Due date:	08/10/07

Product Formulation
Active Ingredient(s)

	% by wt.
n-Alkyl (60% C14, 30% C16, 5% C18, 5% C12) dimethyl benzyl ammonium chloride	3.00
n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride	3.00
Hydrogen peroxide	6.30

BACKGROUND:

The registrant, Sterilex Corp, submitted a one-year Storage Stability and Corrosion Characteristic studies.

FINDINGS:

1. The Product Chemistry Reviewer has received the following document:
   - A study titled "Final Report: Storage Stability of Sterilex Ultra Disinfectant Cleaner Solution 1 (EPA Reg. N0. 63761-8). MRID #467933-01.

2. The Storage stability and corrosion characteristic studies are based on the active ingredients (AIs) n-Alkyl (60% C14, 30% C16, 5% C18, 5% C12) dimethyl benzyl ammonium chloride, and n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chloride. However, the label shows three AIs in which hydrogen peroxide is not included on the one-year storage stability study.

RECOMMENDATION:

1. The registrant must include the active ingredient (AI), hydrogen peroxide, in the one-year storage stability and corrosive characteristic studies.

CONCLUSION:

The one-year Storage Stability and Corrosion Characteristic studies are partially acceptable. The storage stability and corrosion characteristic studies for the AI, hydrogen peroxide must be included.